REMARKS

Claims 1-66 are now pending in the application. Claims 1-34 and 44-66 stand rejected. Claims 35-43 have been previously withdrawn from consideration. Claims 53 and 54 have been cancelled herein, and Claims 44, 52 and 63 have been amended. Support for the amendments can be found throughout the application, drawings and claims as originally filed and, as such, no new matter has been presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

DOUBLE PATENTING REJECTION

Claims 1-66 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-44 of copending Application No. 10/299,969. This rejection is respectfully traversed.

Applicants request that this provisional rejection be held in abeyance until claims have been allowed in at least one of the present Application or U.S. Patent Application No. 10/299,969.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-13,16-20, 44-49 and 51-66 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kesten et al. (U.S. Pat. No. 6,493,575; hereinafter "Kesten"). This rejection is respectfully traversed.

Initially, Applicants note that Kesten discloses a technique for percutaneous myocardial revacularization that includes a catheter 500, a fluoroscope 101 and a

computer workstation 102. The catheter 500 includes a plurality of radio opaque markers that enable the imaging system to locate the catheter 500 in the images acquired by the fluoroscope 101 during the procedure. In use, the fluoroscope 101 acquires images of the catheter 500, and individual frames are downloaded by the workstation 102. The fluoroscope 101 is live during the procedure in that the fluoroscope 101 is rotated between positions to acquire images repeatedly until the procedure is completed (see at least Col. 7, lines 20-30). Then, the computer workstation 102 uses acquired ECG and respiration parameters to improve the quality of the image frames. In this regard, Kesten teaches registering the image frames to the acquired ECG and respiration parameters to remove noise or distortion (motion) from the image frames (image to parameter registration). In contrast to Kesten, independent Claim 1 recites:

> ...an imaging device operable to **capture** image data of the region of the patient **in response to said physiological event**;
>
> * * *
>
> a controller in communication with said anatomical gating device, said imaging device and said tracking device and operable to register said image data with the region of the patient in response to said physiological event, said controller further operable to **superimpose an icon representing the instrument** onto the image data of the region of the patient, based upon the position tracked by said tracking device...(emphasis added).

Independent Claim 44 has been amended to recite:

> ...**capturing image data in response to the physiological event**...(emphasis added).

Independent Claim 52 recites:

> ...**automatically determining an optimized site** to navigate the instrument to...

> **superimposing an icon of the optimized site** and an icon of the location of the catheter on the image data (emphasis added).

Independent Claim 63 has been amended to recite:

> ...an imaging device operable to **capture** image data of the region of the patient **in response to the physiological event**;
>
> * * *
>
> a controller in communication with said anatomical gating device, said imaging device and said tracking device and operable to synchronize captured image data of the region of the patient **in response to a physiological event**, said controller further operable to register said synchronized image data of the region of the patient in response to said physiological event, said controller further operable to **superimpose an icon representing the instrument on to the image data** of the region of the patient, based upon the position tracked by said tracking device...(emphasis added).

In view of the above discussion, Applicants assert that Kesten does not teach, suggest or disclose each and every element of Claims 1, 44, 52 and 63. With regard to Claims 1, 44, 52 and 63, Kesten does not teach, suggest or disclose an imaging device that is operable to capture image data of the region of the patient in response to said physiological event or a controller in communication with an anatomical gating device, the imaging device and a tracking device and operable to register image data acquired by the imaging device with a region of the patient **in response to the physiological event**. Rather, Kesten teaches the use of live fluoroscopy during the entire procedure and not the use of fluoroscopy that is triggered to capture images in response to a physiological event. Further, with regard to Claim 52, Kesten also does not teach, suggest or disclose automatically determining an optimized site to navigate the instrument to or superimposing an icon of the optimized site on the image data. Kesten merely teaches that the user can place a channel mark in a desired location, and does

not disclose automatically optimizing a site to navigate the instrument to. Applicants further note that Kesten does not teach, suggest or disclose superimposing an icon of the optimized site on the image data.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that Kesten does not teach, suggest or disclose each and every element of Claims 1, 44, 52 and 63, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claims 1, 44, 52 and 63 under 35 U.S.C. § 102(b).

In addition, since Claims 2-13, 16-20, 45-49, 51, 55, 56-62 and 64-66 depend directly or indirectly from either independent Claim 1, 44, 52 or 63, Claims 2-13, 16-20, 45-49, 51, 55, 56-62 and 64-66 should be in condition for allowance for at least the reasons set forth for Claims 1, 44, 52 and 63 above. Further, Applicants note that Claims 5 and 64 include independently allowable subject matter as Kesten does not teach, suggest or disclose the use of a tracking device that is selected from the group comprising an electromagnetic tracking device, an optical tracking device, a conductive tracking device, a fiberoptic tracking device and a combination thereof. Additionally, Claim 7 is believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose that the tracking device is an electromagnetic tracking device that has a transmitter coil array operable to generate an electromagnetic field in the region of the patient and a plurality of sensors associated with the instrument operable to sense the electromagnetic field. Claims 10 and 65 are also believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose a controller that can provide an estimated optimized site to navigate the instrument to.

With regard to Claim 12, Applicants also note that Claim 12 is believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose that the position of the instrument is detected at the physiological event and the image device captures the image data at the physiological event such that the position of the instrument is synched with the captured image data. Claim 16 is also believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose a guided biopsy catheter that is operable to be tracked by a tracking device through a region of the patient. Claim 46 is believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose navigating an instrument through a region of the patient, and Claim 47 is believed to have independently allowable subject matter as Kesten does not teach, suggest or disclose sensing a physiological parameter with the instrument.

Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 2-13, 16-20, 45-49, 51, 55, 56-62 and 64-66 under 35 U.S.C. § 102(b).

REJECTION UNDER 35 U.S.C. § 103

Claims 7, 14-16, 21, 22-24, 26-34 and 50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kesten in view of Dumoulin et al. (U.S. Pat. No. 5,377,678; hereinafter "Dumoulin"). Claims 22-24, 26-30 and 32-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haddock (US 2002/0077568; hereinafter "Haddock") in view of Dumoulin. Claim 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haddock in view of Dumoulin and Gilboa et al. (U.S.

Pat. No. 6,711,429; hereinafter "Gilboa"). Claims 31 and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haddock in view of Dumoulin and Kesten. These rejections are respectfully traversed.

Applicants respectfully refer the Office to the remarks regarding Claims 1-13, 16-20, 44-49, and 51-66 for a discussion of the Kesten reference. With regard to Dumoulin, Applicants note that Dumoulin discloses a tracking system that uses radio frequency fields. The radio frequency fields are produced by transmit coils that are driven initially by a master oscillator that generates a signal at a selected frequency (see at least col. 3, lines 24-26 and 34 and Fig. 2A). Dumoulin does not disclose a physiological sensor or gating system or a virtual image system. In addition, Dumoulin does not disclose superimposing an icon representing a location of an optimized site, but at best, discloses only that a superposition means 56 can overlay a symbol 152 on the video signal that represents the calculated position of the invasive device (see at least Col. 3, lines 7-10). With regard to Gilboa, Gilboa is directed to a method for determining the location of a catheter in a body. Gilboa, however, fails to disclose or render obvious each of the elements of the presently pending claims, as noted in the Office Action. Regarding Haddock, Haddock discloses the use of an accelerometer probe to map a vessel. Haddock does not teach, suggest or disclose a controller that estimates an optimized site. In contrast to the cited art, independent Claim 22 recites:

> ...a controller operable to track the position of the instrument with said tracking device and operable to receive the sensed physiological parameter from said sensor, said controller further operable to **estimate the optimized site and superimpose an icon representing the location of the optimized site** and an icon representing the instrument, based on the sensed physiological parameter and on the position of the instrument; and

a display operable to **display the icon of the estimated optimized site** and the icon representing the instrument in the patient (emphasis added).

In view of the above discussion, Applicants assert that Kesten, Dumoulin, and Haddock, singly or in combination, do not teach, suggest or disclose each and every element of Claim 22. In this regard, Kesten does not teach, suggest or disclose a controller that is operable to determine an optimized site to navigate the instrument to, with the controller operable to superimpose an icon of the optimized site on the image data which can be displayed on a display. Kesten merely teaches that the user can place a channel mark in a desired location, and does not disclose estimating an optimized site or displaying an icon of the estimated optimized site. Dumoulin also does not teach, suggest or disclose superimposing an icon representing a location of an optimized site. Applicants also submit that Kesten does not disclose an electromagnetic tracking device as known in the art, and further, modifying Kesten with Dumoulin would change the principle of operation of Kesten, and thus, is improper.

With regard to Haddock, Applicants note that Haddock does not teach, suggest or disclose superimposing an icon representing the instrument, as noted by the Office. Applicants also note that Haddock does not teach, suggest or disclose a controller that is operable to estimate an optimized site to navigate the instrument to or a controller that is operable to superimpose an icon of the optimized site on the image data which can be displayed on a display. As discussed, neither Dumoulin, Kesten, or Gilboa remedy these shortcomings of Haddock. In addition, Applicants note it would be improper to modify Haddock with either Dumoulin or Kesten as it would change the principle of operation of Haddock, and thus, is improper.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that the cited art does not teach, suggest or disclose each and every element of Claim 22, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claim 22 under 35 U.S.C. § 103(a). In addition, since Claims 7, 14-16, 21, 23, 24, 25, 26-34 and 50 depend directly or indirectly from either independent Claim 1, 22 or 44, Claims 7, 14-16, 21, 23, 24, 25, 26-34 and 50 should be in condition for allowance for at least the reasons set forth for Claims 1, 22 and 44 above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 7, 14-16, 21, 23, 24, 25, 26-34 and 50 under 35 U.S.C. § 103(a).

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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By: _____
Richard W. Warner, Reg. No. 38,043
Erica K. Schaefer, Reg. No. 55,861

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

RWW/EKS/chs